K01 1694

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IMPAC

IMPAC Medical Systems, Inc.
www.impac.com

Corporate Office:
100 West Evelyn Avenue
Mountain View, CA 94041-1464
T 650—254 4700
F 650—428 0721

Eastern Region:
43 Thorndike Street
Cambridge, MA 02141-170
T 617—621 2557
F 617—494 6109

AUG 2 9 2001

Tuesday, May 29, 2001

ViewStation, Image Processing System
Premarket Notification (510(k))
Summary of Safety and Effectiveness

Introduction

This document provides a summary of the safety and effectiveness information contained in the ViewStation Premarket Notification (510(k)). The Summary of Safety and Effectiveness contains no confidential or trade secret information and is intended for full public disclosure and distribution. For additional information, feel free to contact the submitter's Management Representative listed below.

Premarket Notification Information

1. Previous Notification Information:
   - a. Previous Premarket Notification — K942346
   - b. Previous Submission Date — 12/28/94
   - c. Product Name — IMAGE RT (renamed ViewStation)
2. Product Information:
   - a. Product Name — ViewStation
   - b. Release Version Number — Version 5.2
3. Classification Information:
   - a. Classification Name — Picture Archiving and Communications System
   - b. Common/Usual Name — Image Processing System
   - c. Product Classification — Class II
   - d. Product Code — 90 LLZ
   - e. Reference — 21 CFR 892.2050
   - f. Review Panel — Radiology
4. Establishment Information:
   - a. Submitter — IMPAC Medical Systems, Inc.
   - b. Submitter Address — 100 West Evelyn Ave., Mountain View, CA 94041
   - c. Establishment Number — 2950347
   - d. Contact — Thomas H. Faris, Director RA/QA
   - e. Contact Phone — 650-623-8807
   - f. Contact Fax — 650-428-0721

Predicate Device

ViewStation is substantially equivalent to the original ViewStation product, which is currently marketed by IMPAC Medical Systems, Inc., and was the subject of Premarket Notification K942346. The new ViewStation and previous ViewStation products are equivalent in intended use and safety and effectiveness.

ViewStation Intended Use

The intended use of ViewStation is to provide health care facility personnel with an efficient and effective means to utilize patient images during the course of therapy or treatment. ViewStation allows users to import, view, annotate, manipulate, enhance, manage, and archive patient images.

ViewStation Indications for Use

ViewStation supports image and information flow among healthcare facility personnel. ViewStation can be used whenever digital images and associated data are the means for communicating information. ViewStation is not intended for use in diagnosis. The images and associated information are stored in a database, providing users access to the information necessary to perform their functions.

Description of the Product

The primary function of ViewStation is to provide a means to more effectively manage image information in a therapy or treatment environment. ViewStation provides the ability to import, view, annotate, manipulate, enhance, manage, and archive patient images during the course of therapy, treatment, and follow-up.

ViewStation imports existing digital images acquired or generated by other products. ViewStation retains the original image, which was acquired or generated by a third party product. With these facts in mind, the goal of ViewStation is to make electronic patient image information more accessible throughout the department. IMPAC is providing a tool to increase department productivity since digital images, unlike films, do not have to be physically transferred from one station to another.

Description of the Change

New automated image processing algorithms have been implemented to perform previously manual processes. The new algorithms:

- determine which of two portal images is the treatment field portal image; and
- employ an edge detection algorithm to identify the treatment field edge in a portal image.

An existing histogram optimization algorithm has been modified to accept new, dynamic inputs derived from the new edge detection algorithm. ViewStation superimposes a polygon representing the field edge from the treatment image onto the open field image of a double exposure portal image series and automatically orders the images so that the open field image is followed by the treatment image when displayed.

Clinical Demonstration of Efficacy

No additional or changed diagnostic or therapeutic claims arise as the result of the change to the ViewStation product. Therefore, demonstration of clinical efficacy is not a required element of this Premarket Notification. Further, clinical performance data is not required for determination of substantial equivalence for this type and class of device.

Device Safety

ViewStation is a medical device that is to be used in a treatment or therapy setting under the use of appropriately trained health care professionals who are responsible for ensuring the correct and accurate use of medical images.

The ViewStation System Hazard Analysis was performed to determine and evaluate all areas that represent potential safety or health hazards during ViewStation system operation. For all system hazards, the hazards, effects, and mitigations have all been documented (SHA2101), reviewed, and implemented. This System Hazard Analysis is reviewed with every change and release of the product, including the above-mentioned changes. Validation and verification activities trace the hazard identification and mitigation through evaluation, design, specification,

implementation, and testing. The Design Review Team has reviewed the product change and System Hazard Analysis and has determined that the product change does not increase health or safety risk to patients, users, or other third parties.

Substantial Equivalence Determination

Improvements have been implemented in the form of an enhancement of ViewStation's existing Edge Detection feature. New algorithms, based upon a well-known field edge detection algorithm, were designed and implemented to automate a previously manual function.

IMPAC has determined and certified that:

A. The intended use of ViewStation remains the same.
B. ViewStation technology has changed by the introduction of a new algorithm to enhance an existing function.
C. The enhanced functionality does not raise any new issue of safety or effectiveness, nor are novel verification or validation methods required to assure safety and effectiveness.
D. The enhanced functionality does not result in a loss of safety or effectiveness of ViewStation.

ViewStation is substantially equivalent to the previously cleared ViewStation product.

Quality System

The fundamental goal of IMPAC's quality program is to provide value to customers and internal operations by producing better and safer products that are less expensive to build and maintain, simpler to use, and easier to support. IMPAC has implemented the IMPAC Quality System to operate in a manner that has proven to be the most efficient and effective. Organizational experience and expertise is built into the management system to ensure that each process consistently meets defined specifications and continuously seeks improvement. All employees receive extensive Quality System training and take pride in the value that they contribute to IMPAC products and processes and to the final customer and their patients.

ViewStation was developed according to the IMPAC Software Design Control Procedure (SDCP). This procedure governs the process by which system and software development are to be planned, defined, implemented, tested, and released.

The IMPAC Quality System was developed in compliance with all of the following standards and regulations:

DOC. ID	TITLE
21 CFR 820	Quality System Regulation
ISO 9001:1994	Quality Systems-Model for Quality Assurance in Design, Development, Production, Installation, and Servicing
ISO 13485:1996	Quality Systems-Medical Devices-Particular Requirements for the Application of ISO 9001
93/42/EEC	Medical Device Directive
EN 46001: 1997	Application of EN ISO 9001 to the Manufacture of Medical Devices
EN 601-1-4: 1996	General Requirements for Safety

Verification and Validation Testing

A Traceability Matrix has been created, based upon the project plan, to ensure the completion of the specification, implementation, and testing of all requirements of the feature enhancement, including performance of full system hazard mitigation and basic operational testing. The System Test Plan defines the overall plan for completing full application, integration, and system testing of ViewStation, while the Test Procedures capture the detailed testing parameters, results, and certification. The included Test Certification Statement certifies that the planned testing requirements were completed successfully. Design Reviews have been performed at the conclusion of each software design and development phase to review and validate the fulfillment of all of the phase requirements and deliverables. All of the above have been completed for ViewStation and representative documents have been included in the Premarket Notification.

Summary of Test Conclusions

IMPAC's Quality Engineering department has completed all product operation and hazard mitigation testing and has certified passing test results. Engineering testing was also performed to ensure that the algorithms and all other technical changes function exactly as intended. The testing demonstrated that the algorithms and all other functionality of ViewStation were successfully implemented.

IMPAC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 29 2001

Mr. Thomas H. Faris
Regulatory Affairs & Quality Assurance
Impac Medical Systems, Inc.
100 West Evelyn Ave.
MOUNTAIN VIEW CA 94041

Re: K011694
Viewstation (Radiation therapy workstation)
Dated: May 29, 2001
Received: May 31, 2001
Regulatory Class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Faris:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4,xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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ViewStation Indications for Use and Intended Use Statement

510(k) Number (if known): K011694

Device Name: **ViewStation, Image Processing System**

Indications for Use:

ViewStation supports image and information flow among health care facility personnel. ViewStation can be used whenever digital images and associated data are the means for communicating information. ViewStation is not intended for use in diagnosis.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011694

Prescription Use ✓